

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700
clizza@saul.com

Of Counsel:

Eric W. Dittmann
Melanie R. Rupert
Isaac S. Ashkenazi
Dana Weir
M. Ryan Meuth
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166

*Attorneys for Plaintiff
Helsinn Healthcare S.A.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A.,

Plaintiff,

v.

GLAND PHARMA LIMITED,

Defendant.

Civil Action No. 22-4635 (ZNQ)(LHG)

(Filed Electronically)

**HELSINN HEALTHCARE S.A.'S ANSWER TO
GLAND PHARMA LIMITED'S COUNTERCLAIMS**

Plaintiff Helsinn Healthcare S.A. ("Helsinn" or "Plaintiff"), by and through its undersigned attorneys, hereby replies to the numbered paragraphs of the counterclaims of Defendant/Counterclaimant Gland Pharma Limited ("Gland"), set forth in "Gland's Amended Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint," filed on October 11, 2022 (D.I. 25) (hereinafter, "counterclaims") as follows:

THE PARTIES

1. Upon information and belief, Plaintiff admits the allegations of counterclaim

paragraph 1.

2. Plaintiff admits the allegations of counterclaim paragraph 2.

JURISDICTION AND VENUE

3. Counterclaim paragraph 3 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff does not contest that this Court has subject matter jurisdiction over Gland's counterclaims for purposes of this action. Plaintiff admits that an actual justiciable controversy exists between Plaintiff and Gland regarding Gland's infringement of U.S. Patent No. 8,426,450 ("the '450 patent"), U.S. Patent No. 8,895,586 ("the '586 patent"), U.S. Patent No. 9,186,357 ("the '357 patent"), U.S. Patent No. 9,403,772 ("the '772 patent"), U.S. Patent No. 9,908,907 ("the '907 patent"), U.S. Patent No. 10,208,073 ("the '073 patent"), U.S. Patent No. 10,624,911 ("the '911 patent"), U.S. Patent No. 10,717,721 ("the '721 patent"), U.S. Patent No. 10,828,297 ("the '297 patent"), and U.S. Patent No. 11,312,698 ("the '698 patent") (collectively, "the patents-in-suit"). Plaintiff denies the legal sufficiency of Gland's counterclaims, and further denies that Gland is entitled to the declarations it seeks. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 3.

4. Counterclaim paragraph 4 states conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff does not contest that this Court has personal jurisdiction over Helsinn for purposes of this action. Plaintiff denies the legal sufficiency of Gland's counterclaims, and further denies that Gland is entitled to the declarations it seeks. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 4.

5. Counterclaim paragraph 5 states a legal conclusion to which no reply is required. To the extent a reply is required, Plaintiff does not contest that this Court has personal

jurisdiction over Helsinn for purposes of this action. Plaintiff denies the legal sufficiency of Gland's counterclaims, and further denies that Gland is entitled to the declarations it seeks. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 5.

6. Counterclaim paragraph 6 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff does not contest that venue is proper in this Court as to Gland's counterclaims for purposes of this action. Plaintiff denies the legal sufficiency of Gland's counterclaims, and further denies that Gland is entitled to the declarations it seeks. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 6.

BACKGROUND

7. Plaintiff admits that Helsinn is the holder of approved New Drug Application ("NDA") No. 210493. Plaintiff admits that NDA No. 210493 was first approved by the U.S. Food and Drug Administration ("FDA") on April 19, 2018. Plaintiff admits that it manufactures and sells fosnetupitant chloride hydrochloride palonosetron hydrochloride drug products for intravenous infusion under the brand name Akynzeo[®] pursuant to NDA No. 210493.

8. Plaintiff admits the allegations of counterclaim paragraph 8.

9. Upon information and belief, Plaintiff admits that Gland filed ANDA No. 217374 ("Gland's ANDA") seeking approval to market EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg/0.25 mg per 20 mL single-dose vials for injection ("Gland's ANDA Product").

10. Upon information and belief, Plaintiff admits that as of the time Gland's ANDA was filed, each of the patents-in-suit (except for the '698 patent) was listed in the FDA

publication titled “*Approved Drug Products with Therapeutic Equivalence Evaluations*” (commonly known as “the Orange Book”) as covering Akynzeo[®] and/or its use in connection with NDA No. 210493. Plaintiff admits the Orange Book currently lists each of the patents-in-suit as covering Akynzeo[®] and/or its use in connection with NDA No. 210493. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 10.

11. Plaintiff admits that the patents-in-suit are listed in the Orange Book as covering Akynzeo[®] and/or its use in connection with NDA No. 210493. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 11.

12. Plaintiff admits that Gland has represented that ANDA No. 217374 includes a certification that each of the claims of the patents-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Gland’s ANDA Product (together, “Gland’s Paragraph IV Certifications”). The remainder of counterclaim paragraph 12 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 12.

13. Plaintiff admits that Helsinn received a letter sent via Federal Express and dated June 2, 2022 stating that ANDA No. 217374 includes Paragraph IV Certifications alleging, *inter alia*, that the claims of the ’450 patent, the ’586 patent, the ’357 patent, the ’772 patent, the ’907 patent, the ’073 patent, the ’911 patent, the ’721 patent, and the ’297 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Gland’s ANDA Product (“Gland’s June 2, 2022 Notice Letter”). The remainder of counterclaim paragraph 13 contains conclusions of law to which no reply is required. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 13.

14. Plaintiff admits that Helsinn received Gland's June 2, 2022 Notice Letter but denies that Gland's June 2, 2022 Notice Letter provides a detailed statement of the factual and legal bases for Gland's Paragraph IV certifications. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 14.

15. Plaintiff admits that Helsinn received a letter sent via Federal Express and dated July 11, 2022 stating that ANDA No. 217374 includes Paragraph IV Certification alleging, *inter alia*, that the claims of the '698 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Gland's ANDA Product ("Gland's July 11, 2022 Notice Letter"). The remainder of counterclaim paragraph 15 contains conclusions of law to which no reply is required. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 15.

16. Plaintiff admits that Helsinn received Gland's July 11, 2022 Notice Letter, but denies that Gland's July 11, 2022 Notice Letter provides a detailed statement of the factual and legal bases for Gland's Paragraph IV certification. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 16.

17. Plaintiff admits that it received Gland's June 2, 2022 Notice Letter and Gland's July 11, 2022 Notice Letter. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 17.

18. Plaintiff admits that on July 18, 2022, Helsinn filed a Complaint against Gland in this Court alleging, *inter alia*, that Gland's submission to the FDA of ANDA No. 217374, including the accompanying Paragraph IV certifications pursuant to U.S.C. § 355(b)(2)(A)(iv), constitutes infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A), and that Gland's manufacture, use, offer to sell, within the United States, and/or importation into the United States

of Gland's ANDA Product would further infringe one or more claims of the patents-in-suit pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g). To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 18.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '450 PATENT)

19. Plaintiff incorporates by reference its responses to paragraphs 1 through 18 of Gland's counterclaims as if fully set forth herein.

20. Plaintiff denies the allegations of counterclaim paragraph 20.

21. Plaintiff denies the allegations of counterclaim paragraph 21.

22. Plaintiff denies the allegations of counterclaim paragraph 22.

23. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 23 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 23.

24. Counterclaim paragraph 24 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 24.

25. Plaintiff denies the allegations of counterclaim paragraph 25.

SECOND COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '450 PATENT)

26. Plaintiff incorporates by reference its responses to paragraphs 1 through 25 of Gland's counterclaims as if fully set forth herein.

27. Plaintiff denies the allegations of counterclaim paragraph 27.

28. Plaintiff denies the allegations of counterclaim paragraph 28.

29. Plaintiff denies the allegations of counterclaim paragraph 29.

THIRD COUNTERCLAIM
**(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '586 PATENT)**

30. Plaintiff incorporates by reference its responses to paragraphs 1 through 29 of Gland's counterclaims as if fully set forth herein.

31. Plaintiff denies the allegations of counterclaim paragraph 31.

32. Plaintiff denies the allegations of counterclaim paragraph 32.

33. Plaintiff denies the allegations of counterclaim paragraph 33.

34. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 34 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 34.

35. Counterclaim paragraph 35 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the

extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 35.

36. Plaintiff denies the allegations of counterclaim paragraph 36.

FOURTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '586 PATENT)

37. Plaintiff incorporates by reference its responses to paragraphs 1 through 36 of Gland's counterclaims as if fully set forth herein.

38. Plaintiff denies the allegations of counterclaim paragraph 38.

39. Plaintiff denies the allegations of counterclaim paragraph 39.

40. Plaintiff denies the allegations of counterclaim paragraph 40.

FIFTH COUNTERCLAIM
**(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '357 PATENT)**

41. Plaintiff incorporates by reference its responses to paragraphs 1 through 40 of Gland's counterclaims as if fully set forth herein.

42. Plaintiff denies the allegations of counterclaim paragraph 42.

43. Plaintiff denies the allegations of counterclaim paragraph 43.

44. Plaintiff denies the allegations of counterclaim paragraph 44.

45. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 45 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 45.

46. Counterclaim paragraph 46 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 46.

47. Plaintiff denies the allegations of counterclaim paragraph 47.

SIXTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '357 PATENT)

48. Plaintiff incorporates by reference its responses to paragraphs 1 through 47 of Gland's counterclaims as if fully set forth herein.

49. Plaintiff denies the allegations of counterclaim paragraph 49.

50. Plaintiff denies the allegations of counterclaim paragraph 50.

51. Plaintiff denies the allegations of counterclaim paragraph 51.

SEVENTH COUNTERCLAIM
**(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '772 PATENT)**

52. Plaintiff incorporates by reference its responses to paragraphs 1 through 51 of Gland's counterclaims as if fully set forth herein.

53. Plaintiff denies the allegations of counterclaim paragraph 53.

54. Plaintiff denies the allegations of counterclaim paragraph 54.

55. Plaintiff denies the allegations of counterclaim paragraph 55.

56. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested

relief. The remainder of counterclaim paragraph 56 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 56.

57. Counterclaim paragraph 57 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 57.

58. Plaintiff denies the allegations of counterclaim paragraph 58.

EIGHTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '772 PATENT)

59. Plaintiff incorporates by reference its responses to paragraphs 1 through 58 of Gland's counterclaims as if fully set forth herein.

60. Plaintiff denies the allegations of counterclaim paragraph 60.

61. Plaintiff denies the allegations of counterclaim paragraph 61.

62. Plaintiff denies the allegations of counterclaim paragraph 62.

NINTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '907 PATENT)

63. Plaintiff incorporates by reference its responses to paragraphs 1 through 62 of Gland's counterclaims as if fully set forth herein.

64. Plaintiff denies the allegations of counterclaim paragraph 64.

65. Plaintiff denies the allegations of counterclaim paragraph 65.

66. Plaintiff denies the allegations of counterclaim paragraph 66.

67. Plaintiff admits that Gland purports to assert counterclaims that arise under the

Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 67 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 67.

68. Counterclaim paragraph 68 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 68.

69. Plaintiff denies the allegations of counterclaim paragraph 69.

TENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '907 PATENT)

70. Plaintiff incorporates by reference its responses to paragraphs 1 through 69 of Gland's counterclaims as if fully set forth herein.

71. Plaintiff denies the allegations of counterclaim paragraph 71.

72. Plaintiff denies the allegations of counterclaim paragraph 72.

73. Plaintiff denies the allegations of counterclaim paragraph 73.

ELEVENTH COUNTERCLAIM
**(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '073 PATENT)**

74. Plaintiff incorporates by reference its responses to paragraphs 1 through 73 of Gland's counterclaims as if fully set forth herein.

75. Plaintiff denies the allegations of counterclaim paragraph 75.

76. Plaintiff denies the allegations of counterclaim paragraph 76.

77. Plaintiff denies the allegations of counterclaim paragraph 77.

78. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 78 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 78.

79. Counterclaim paragraph 79 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 79.

80. Plaintiff denies the allegations of counterclaim paragraph 80.

TWELFTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '073 PATENT)

81. Plaintiff incorporates by reference its responses to paragraphs 1 through 80 of Gland's counterclaims as if fully set forth herein.

82. Plaintiff denies the allegations of counterclaim paragraph 82.

83. Plaintiff denies the allegations of counterclaim paragraph 83.

84. Plaintiff denies the allegations of counterclaim paragraph 84.

THIRTEENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '911 PATENT)

85. Plaintiff incorporates by reference its responses to paragraphs 1 through 84 of Gland's counterclaims as if fully set forth herein.

86. Plaintiff denies the allegations of counterclaim paragraph 86.

87. Plaintiff denies the allegations of counterclaim paragraph 87.

88. Plaintiff denies the allegations of counterclaim paragraph 88.

89. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 89 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 89.

90. Counterclaim paragraph 90 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 90.

91. Plaintiff denies the allegations of counterclaim paragraph 91.

FOURTEENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '911 PATENT)

92. Plaintiff incorporates by reference its responses to paragraphs 1 through 91 of Gland's counterclaims as if fully set forth herein.

93. Plaintiff denies the allegations of counterclaim paragraph 93.

94. Plaintiff denies the allegations of counterclaim paragraph 94.

95. Plaintiff denies the allegations of counterclaim paragraph 95.

FIFTEENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '721 PATENT)

96. Plaintiff incorporates by reference its responses to paragraphs 1 through 95 of Gland's counterclaims as if fully set forth herein.

97. Plaintiff denies the allegations of counterclaim paragraph 97.

98. Plaintiff denies the allegations of counterclaim paragraph 98.

99. Plaintiff denies the allegations of counterclaim paragraph 99.

100. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 100 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 100.

101. Counterclaim paragraph 101 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 101.

102. Plaintiff denies the allegations of counterclaim paragraph 102.

SIXTEENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '721 PATENT)

103. Plaintiff incorporates by reference its responses to paragraphs 1 through 102 of Gland's counterclaims as if fully set forth herein.

104. Plaintiff denies the allegations of counterclaim paragraph 104.

105. Plaintiff denies the allegations of counterclaim paragraph 105.

106. Plaintiff denies the allegations of counterclaim paragraph 106.

SEVENTEENTH COUNTERCLAIM
**(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '297 PATENT)**

107. Plaintiff incorporates by reference its responses to paragraphs 1 through 106 of Gland's counterclaims as if fully set forth herein.

108. Plaintiff denies the allegations of counterclaim paragraph 108.

109. Plaintiff denies the allegations of counterclaim paragraph 109.

110. Plaintiff denies the allegations of counterclaim paragraph 110.

111. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 111 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 111.

112. Counterclaim paragraph 112 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the

extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 112.

113. Plaintiff denies the allegations of counterclaim paragraph 113.

EIGHTEENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '297 PATENT)

114. Plaintiff incorporates by reference its responses to paragraphs 1 through 113 of Gland's counterclaims as if fully set forth herein.

115. Plaintiff denies the allegations of counterclaim paragraph 115.

116. Plaintiff denies the allegations of counterclaim paragraph 116.

117. Plaintiff denies the allegations of counterclaim paragraph 117.

NINETEENTH COUNTERCLAIM
**(DECLARATION OF NON-INFRINGEMENT
OF ANY VALID CLAIM OF THE '698 PATENT)**

118. Plaintiff incorporates by reference its responses to paragraphs 1 through 117 of Gland's counterclaims as if fully set forth herein.

119. Plaintiff denies the allegations of counterclaim paragraph 119.

120. Plaintiff denies the allegations of counterclaim paragraph 120.

121. Plaintiff denies the allegations of counterclaim paragraph 121.

122. Plaintiff admits that Gland purports to assert counterclaims that arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 100, *et seq.* Plaintiff admits that a definite, concrete, real, substantial, and justiciable controversy exists between Gland and Plaintiff, but denies that Gland is entitled to its requested relief. The remainder of counterclaim paragraph 122 contains conclusions of law to which no reply is required. To the extent a reply is required, and to the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 122.

123. Counterclaim paragraph 123 contains conclusions of law to which no reply is required. To the extent a reply is required, Plaintiff admits that a patent owner has the burden to prove patent infringement, but denies that Helsinn will not be able to meet that burden. To the extent not otherwise admitted, Plaintiff denies the remaining allegations of counterclaim paragraph 123.

124. Plaintiff denies the allegations of counterclaim paragraph 124.

TWENTIETH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '698 PATENT)

125. Plaintiff incorporates by reference its responses to paragraphs 1 through 124 of Gland's counterclaims as if fully set forth herein.

126. Plaintiff denies the allegations of counterclaim paragraph 126.

127. Plaintiff denies the allegations of counterclaim paragraph 127.

128. Plaintiff denies the allegations of counterclaim paragraph 128.

PRAYER FOR RELIEF

Plaintiff denies that Gland is entitled to any relief based on its counterclaims or any remedy or relief whatsoever. Plaintiff further denies that Gland is entitled to relief based upon any of the affirmative defenses identified in D.I. 25.

* * * *

Helsinn further denies each and every allegation of Gland's Counterclaims not expressly admitted or otherwise responded to above.

Dated: October 25, 2022

OF COUNSEL:

Eric W. Dittmann
Melanie R. Rupert
Isaac S. Ashkenazi
Dana Weir
M. Ryan Meuth
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700
clizza@saul.com

*Attorneys for Plaintiff
Helsinn Healthcare S.A.*